

## Meeting Minutes

<b>Institution:</b>	The Sir Mortimer B. Davis Jewish General Hospital		
<b>Meeting Date:</b>	May 12, 2026		
<b>Meeting Time</b>	10:00 AM Eastern Time		
<b>Meeting Type:</b>	Virtual Platform Teleconference (Remote) Open to the Public		
<b>Members in Attendance:</b>	<b>Member</b>	<b>Voting</b>	<b>Member Type</b>
	Bavaret, Tammy	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	McGirr, Becky	Yes	Core Member: Biosafety Expert/HGT Expert
	Venugopal, Devi	Yes	Local Unaffiliated Member
	Nair, Amogh	Yes	Local Unaffiliated Member
	Scarborough, Robert	Yes	Biological Safety Officer
<b>Invited Members Not in Attendance:</b>	None		
<b>Guests:</b>	Loutochin, Oleg; Sullivan, Thomas; Sadeghialavi, Zohreh		
<b>Staff:</b>	Smith, Jennifer		

**Call to Order:** The IBC Chair called the meeting to order at 10:02 AM. A quorum was present as defined in the Sabai IBC Charter.

**Conflicts of Interest:** The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

**Public Comments:** No public comments were made prior to or at the meeting.

**Review of Prior Business:** None

**Previous Meeting Minutes:** Minutes from 4/30/26 were approved by the IBC with no changes. There were no votes against and no abstentions.

## New Business:

<b>PI:</b>	McPherson, Victor
<b>Sponsor:</b>	Ferring Pharmaceuticals A/S
<b>Protocol:</b>	ABLE-22 A phase 3, randomized, multi-centre, open label trial to evaluate the safety and efficacy of intravesical nadofaragene firadenovec alone or in combination with chemotherapy (gemcitabine and docetaxel) or immunotherapy (pembrolizumab) in subjects with high-grade Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC)
<b>Review Type:</b>	Initial Review
<b>NIH Guidelines Section:</b>	III-C-1

**Trial Summary:** ABLE-22 (Trial Code 000434) is a randomized, open-label Phase III clinical trial sponsored by Ferring Pharmaceuticals A/S designed to evaluate the safety and efficacy, including reinduction, of intravesical instillation of nadofaragene firadenovec in subjects with high-grade Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The study agent nadofaragene firadenovec is a recombinant, replication-deficient type 5 adenovirus vector containing the transgene that encodes the human interferon- $\alpha$ 2b (IFN- $\alpha$ 2b) gene. The investigational product (IP) is administered by intravesical instillation.

**Biosafety Containment Level (BSL):** The study agent nadofaragene firadenovec is based on a recombinant Risk Group 2 adenovirus containing more than two-thirds of the native genome, requiring the use of BSL-2/CL-2 containment under the NIH Guidelines.

### Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor’s study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
  - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills, splashes, or aerosols of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

## Meeting Minutes

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
  - The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
  - The Site confirmed that staff members receive Bloodborne Pathogens training.
  - Occupational Health Recommendations: The Sponsor indicates that immunocompromised persons, including those receiving immunosuppressant therapy, maybe at risk for disseminated adenovirus infection because of the possible presence of low levels of replication-competent adenovirus in nadofaragene firadenovec. Thus, individuals who are immunosuppressed or immune-deficient should not prepare, administer, or come into contact with the study agent.
  - The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.
- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials, and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - In response to a question from the Committee, the Site confirmed that the BSC recertification is scheduled for next week and they will send Sabai the updated certification report when it is available.
    - The Committee recommended that the Site remove the regular garbage bin from the dosing room during administration to ensure biohazardous waste is not disposed of into the regular garbage.
    - In response to a question from the Committee, the Site confirmed that isopropyl alcohol is only used by the pharmacy as part of the rinsing process, after other disinfectants have been used.
    - The Committee noted the biohazard signs on the pharmacy doors are faded and recommended that the Site reprint the door biohazard signs. The Site had no concerns.
    - In response to a question from the Committee, the Site confirmed that they have the shipping training certification easily accessible.

**Motion:** A motion of Full Approval for the study at CL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

## Meeting Minutes

**Review of Incidents:** Nothing to report.

**IBC Training:** Nothing to report.

**Reminder of IBC Approval Requirements.**

**Adjournment:** The IBC Chair adjourned the meeting at 10:44 AM.

**Post-Meeting Pre-Approval Note:** None